



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/493,423 01/29/00 NEGUS

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EXAMINER

FARAH, A

ART UNIT

PAPER NUMBER

3739

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/493,423

Applicant(s)

Negus et al.

Examiner

A. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 7 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy-Chutorian U. S. Pat. No. 5,891,133 in view of March et al. U. S. Pat. No. 5,840,059.

Murphy-Chutorian discloses methods and apparatuses related to laser-assisted intra-coronary transmyocardial revascularization. More particularly, Murphy-Chutorian's invention is directed to improved methods and apparatuses for directing an interventional catheter device via percutaneous or other entry into the coronary artery. He further teaches that a laser energy delivery means is then positioned inside the coronary artery to create a plurality of small channels through the coronary artery into the tissue of myocardium. In addition, Murphy-Chutorian discloses that his catheter has a plurality of branched arms whereby each branched arm is individually capable of receiving a laser delivery means, visualization or marking means, or other tools. Here, the branched arms are treated as catheter subsystems.

In a preferred embodiment, Murphy-Chutorian discloses that a radio-opaque material disposed near the distal end of the interventional device is used for assisting in visualization of

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the device during the procedure via a fluoroscope or other suitable viewing means. See column 7, lines 24-28. Murphy-Chutorian further teaches the uses and the advantages of drug therapy for the treatment of coronary artery blockage. See column 2, lines 34-38.

However, although Murphy-Chutorian teaches the advantages of drug therapy for the treatment of occlusive coronary artery, he does not use drug therapy with his invention. March et al. discloses an alternative system and method for treating a patient's heart which comprises a means to form channels in the heart wall and a means to deliver therapeutic or diagnostic agents into the wall. March et al. further teaches the potential benefits of therapeutic agents for the treatment. See column 1, lines 11-14 and 22-31. Thus, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Murphy-Chutorian with March et al. to deliver therapeutic agent into patient's heart in order to relieve arterial blockage as taught by Murphy-Chutorian or to direct genetically engineered materials to the cells of a desired treatment area as taught by March et al.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy-Chutorian U. S. Pat. No. 5,891,133 and March et al. U. S. Pat. No. 5,840,059 as applied to claims 1 and 2 above, and further in view of Mueller U. S. Pat. No. 5,725,523.

Murphy-Chutorian and March et al. have been described above. However, although Murphy-Chutorian discloses the use of visualization or viewing means, neither of them shows an external imaging device positioned outside the patient. Mueller discloses an alternative laser-assisted transmyocardial revascularization device and method including a video monitor, 78, for

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viewing the treatment process. See Fig. 3 of Mueller . Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify Murphy-Chutorian with March et al. and with Mueller to provide an external imaging device which is positioned outside the patient in order to provide a real-time images or other images as the procedure is taking place.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

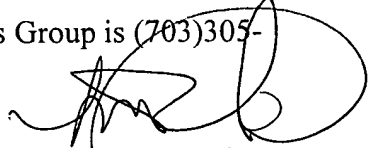
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|----------------------------|--------------------------|
| 1. Ellis et al. | U. S. Pat. No. 6,056,743 |
| 2. Abela et al. | U. S. Pat. No. 5,769,843 |
| 3. Chime et al. | U. S. Pat. No. 5,873,366 |
| 4. Aita et al. | U. S. Pat. No. 5,380,316 |
| 5. Aita et al. | U. S. Pat. No 5,389,096 |
| 6. Murphy-Chutorian et al. | U. S. Pat. No. 5,925,012 |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703)305-5787.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms.

Linda Dvorak, can be reached on (703) 308-0994. The fax number for this Group is (703)305-

3590.


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